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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,356	11/25/2003	Antonio Cutando Soriano	285.1001US	4724
7590 02/03/2009 DAVIDSON, DAVIDSON & KAPPEL, LLC 14th Floor 485 Seventh Avenue New York, NY 10018				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT 1612		PAPER NUMBER		
MAIL DATE 02/03/2009		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/722,356

**Applicant(s)**

SORIANO ET AL.

**Examiner**

Snigdha Maewall

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### Summary

1. Receipt of applicants arguments/Remarks and amended claims filed on 09/11/08 is acknowledged.

New claims 15-17 have been added in this application.

Claims **1-8 and 13-17** are under prosecution.

The rejections made in previous office action that has not been repeated herein are withdrawn.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 recites the limitation "essential oil". The metes and bounds of the claim is not defined. It is not clear what applicant refers to as being essential. Appropriate correction is required. Claims 7 and 13 recite the limitation as where in the active consists of Melatonin. It is not clear to the examiner how can the active be only melatonin when the composition also comprises antioxidants and hydrophilic carriers.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neigut (USP 6,048,886) in view of US Cutler (USP 5,900,230) or vice versa.

Neigut discloses compositions and methods for the application of those compositions in order to treat biological surfaces, especially the skin (abstract). The composition disclosed contains antioxidants such as melatonin (abstract). Melatonin may be present at weight percentages ranging from 0.1% to 99% (see column 5, lines 25-30). The antioxidant greatly reduces the damage to skin and also improves the immunocompetence of the cells (see column 2, lines 15-35). The reference teaches preparation with a carrier in examples and discloses that if desired, the formulation can be produced as an ointment or emulsions by adding emulsifiers, thickeners and surfactants during the manufacturing process (see column 9, lines 60-66).

Neigut does not specifically teach preservatives or hydrophobic and hydrophilic excipients. Cutler discloses dental product for the treatment of periodontal diseases (see abstract). The dental product is in the form of dentifrice pastes or gels, powders,

granules (see abstract). The reference discloses melatonin from (0.1% to 1%) and antioxidant (claimed as active-autooxidant) such as ascorbic acid and coenzyme Q10. preservative such as paraben (see claim 17. Ethylcellulose ( reads on hydrophobic excipient as claimed ) and hydrophilic excipients such as polysaccharides are disclosed in claim 10 and 11.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate preservative and hydrophilic/hydrophobic excipients as taught by Cutler et al. because Cutler is directed towards dental product such as pastes and gels and Neigut suggests use of the disclosed formulation for oral, mouth surfaces which would benefit from the application of such preparations. Since Neigut discloses that melatonin acts as antioxidant and immunostimulant, it would have been obvious to the one of ordinary skilled in the art to prepare an oral hygiene product with antioxidant and immunostimulating activity for human and animal with a reasonable expectation of success.

### ***Response to Arguments***

6. Applicant's arguments filed 09/11/08 have been fully considered but they are not persuasive.

Applicant argues that the instant language of "consists of melatonin" excludes presence of any other active in the composition. Since Cutler and Neigut both have other actives, the combination of references to prove obviousness is not appropriate. Applicant's arguments are not persuasive. The prior art teaches the limitations of the claimed

composition. The references do not dissuade addition of other ingredients at the same time. Applicant argues that the instant claims recite specific preservatives. This is not persuasive to overcome the obviousness rejection because as discussed above Neigut discloses melatonin and Cutler discloses hydrophilic and hydrophobic excipients along with melatonin as immunostimulant. Applicants combination is obvious over the teachings of prior art. Applicant is doing piece meal analysis of the references and is looking for exact statements in the prior art as claimed. However, the rejection is of obviousness not anticipation. Burden is on the applicant to show how the presence of other excipients would affect the properties of the claimed invention. Furthermore, claims 1 and 8 do not recite "consisting of" language and therefore, exclusion of any other limitation from being read in claims is not excluded during prosecution due to the open ended language of claims.

7. Claims 1-8 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masterson USP 6,200,550 in view of US Cutler (USP 5,900,230) or Neigut (USP 6,048,886).

Masterson discloses toothpastes comprising 0.2 to 2 percent by weight of melatonin (column 7, line 2). The compositions contain conventional hydrophobic and hydrophilic excipients and also contain preservatives (column 8, line 51), with sorbic acid being used in working example 4 (column 12).

The reference does not disclose antioxidants. Cutler discloses dental product for the treatment of periodontal diseases (see abstract). The dental product is in the form of dentifrice pastes or gels, powders, granules (see abstract). The reference discloses melatonin from (0.1% to 1%) and antioxidant (claimed as active-autooxidant) such as ascorbic acid and coenzyme Q10. Preservatives such as paraben are disclosed (see claim 17). Ethylcellulose (reads on hydrophobic excipient as claimed) and hydrophilic excipients such as polysaccharides are disclosed in claims 10 and 11. Essential oils are disclosed in claim 1. It should be noted regarding claim 14 that the products composition is disclosed in prior art and product being used in the form of animal feed is an intended use of the product/composition, as such bears no patentable weight. Neuget teaches antioxidant such as COQ.sub.10 along with vitamin A, B and C and further teaches that melatonin stimulates natural antioxidants and improve DNA repair and enhances the immune system. It would have been obvious to one of ordinary skilled in the art at the time the instant invention was made to incorporate ascorbic acid in the composition forwarded by Masterson et al. because antioxidants reduce the oxidative damage to the skin. A skilled artisan would thus have been motivated to combine the antioxidants to the Masterson composition and arrived at the claimed invention with the reasonable expectation of success.

### ***Response to Arguments***

8. Applicant's arguments filed 09/11/08 have been fully considered but they are not persuasive.

Applicant argues that Claims 1, 7, 8 and 13 exclude the presence of any other actives of Masterson. The arguments are not persuasive because firstly, claims 1 and 8 do not recite consisting of language. The prior art as discussed above does teach the claimed ingredients and limitations. Masterson patent teaches melatonin and Cutler teaches antioxidants. Optimization of various amounts is a manipulable parameter absent evidence to contrary. Since the claims are drawn to product, its application is an intended use as claimed in claim 14 as the product being used as animal feed. There is nothing in the prior art which teaches or suggests that the presence of other actives would affect the properties of the claimed melatonin composition wherein the references explicitly teach melatonin in the composition. Therefore, the combination of references would have been obvious over the teachings of prior art.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

Art Unit: 1612

Customer Service Representative or access to the automated information system, call  
800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore /

Primary Examiner, Art Unit 1612